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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,200	12/05/2001	Michael R. Wessels	B00801/70237 (ERG/MXA)	8283
7590 09/09/2005 Edward R. Gates c/o Wolf, Greenfield & Sacks, P.C. Federal Reserve Plaza 600 Atlantic Avenue Boston, MA 02210-2211			EXAMINER FORD, VANESSA L	
			ART UNIT 1645	PAPER NUMBER
DATE MAILED: 09/09/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

*Mc*

**Office Action Summary**

Application No.

10/005,200

Applicant(s)

WESSELS ET AL.

Examiner

Vanessa L. Ford

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 12-19, 21-23, 45 and 68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12-19, 21-23, 45 and 68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**FINAL ACTION**

1. This action is responsive to Applicant's amendment and response filed May 12, 2005. Claims 1, 7-8, 23, 45 and 68 have been amended. Claims 9-11, 20, 24-44, 46-67 and 69-162 have been cancelled.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

***Rejections Withdrawn***

3. In view of Applicant's amendment and remarks the following rejections are withdrawn:
  - a) rejection of claims 1-8, 12-19, 21-23, 45 and 68 under 35 U.S.C. 112, second paragraph, page 2, paragraph 2.
  - b) rejection of claims 1-8, 12-19, 21-23, 45 and 68 under 35 U.S.C. 103(a) pages 4-5, paragraph 5.

It should be noted that the Examiner is viewing hyaluronic acid and hyaluronate to be synonymous terms.

***New Grounds of Rejection Necessitated by Amendment***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-8, 12-19, 21-23, 45 and 68 are rejected under 35 U.S.C. 103(a) as unpatentable over Fillit et al (*J Exp. Med*, Volume 164, September 1986) in view of Yutaka (*JP 6 107 550*, published April 19, 1994) and further in view of Schragar et al (*J. Clin. Invest.*, Volume 98, Number 9, November 1996).

Claims 1-8, 12-19, 21-23, 45 and 68 are drawn to a method of prophylactically treating a subject not exhibiting symptoms of a streptococcal or staphylococcal infection comprising administering orally to a subject in need of such prophylactic treatment an agent that binds to a hyaluronic acid-binding region of a CD44 protein in an amount effective to interfere with the adhesion of streptococcal bacteria to CD44 protein in the subject and inhibit streptococcal colonization of the pharynx wherein either one or both of the following conditions applies: the treatment is free of Echinacea or the agent is administered in a dose greater than 0.2 mg wherein the agent is hyaluronic acid.

Fillit et al teach a method of immunizing rabbits (subjects) by administering to the rabbits encapsulated group A streptococci (capsule containing hyaluronic acid) (see the Abstract). Fillit et al teach that 1 ml of hyaluronate was administered to rabbits by

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intravenous injection (page 764). Fillit et al teach that hyaluronate was immunogenic in rabbits (page 774). Fillit et al teach a method of immunizing subjects (rabbits) with hyaluronate that do not exhibit symptoms of a streptococcal infection.

Fillit et al do not teach oral administration of hyaluronic acid.

Yutaka teaches that hyaluronic acid can be administered orally to treat subjects that suffer from infections such as amygdalitis, pharyngitis and laryngitis which are infections caused by streptococcal and staphylococcal bacteria (see the Abstract). Yutaka teaches that hyaluronic acid can adhere to mucous membrane to promote healing and protection of the mucous membrane (see the Abstract).

Fillit et al and Yutaka et al as combined above do not teach that hyaluronic acid interferes with adhesion of bacteria to the CD44 protein..

Schrager et al teach that the hyaluronic capsule decreases the overall adhesiveness of GAS to epithelial cells (1714). Schrager et al suggests that the hyaluronic capsule itself may act as an adhesin for attachment of diverse strains of GAS to the hyaluronic acid-binding glycoprotein CD44 (page 1709). Schrager et al teach that because the hyaluronic capsule forms the outermost layer on GAS cells, the capsule may modulate or prevent interaction of bacterial cell wall components or surface proteins with host cell receptors (page 1714). The prior art references as combined teach the treatment is free of Echinacea.

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Claim limitations such as dosage requirements, time periods and number of administrations are being viewed as limitations of optimizing experimental parameters”.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to orally administer hyaluronic acid (hyaluronic capsule) to treat streptococcal infections because Yutaka teaches that hyaluronic acid can adhere to mucous membrane to promote healing and protection of the mucous membrane and Schragar et al suggests that the hyaluronic capsule itself may act as an adhesin for attachment of diverse strains of GAS to the hyaluronic acid-binding glycoprotein CD44. It would be expected barring evidence to the contrary, that administering hyaluronic acid to subjects would be effective in treating streptococcal and staphylococcal infections because Schragar et al teach that because the hyaluronic capsule forms the outermost layer on GAS cells, the capsule may modulate or prevent interaction of bacterial cell wall components or surface proteins with host cell receptors.

### ***Status of Claims***

5. No claims allowed.
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

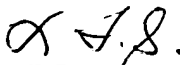
7. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Vanessa L. Ford  
Biotechnology Patent Examiner  
August 31, 2005

  
**LYNETTE R. F. SMITH**  
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